

Amendment and Response
Applicants: Bruce S. Ellingboe et al.
Serial Number: 09/963,878

Attorney Docket: CV-0290US

REMARKS

Original claims 1 - 12 are pending.

Drawings

Objection has been made to Figures 3A, 3A-1 through 3A-4, 3B and 3B-1 through 3B-4. Figure 3A indicates that Figures 3A-1 through 3A-4 are to be arranged in a quadrant, as shown in Figure 3A, to represent an embodiment of a disposable cartridge assembly in association with an embodiment of a blood perfusion system according to an embodiment of this invention. Figure 3B indicates that Figures 3B-1 through 3B-4 are to be arranged in a quadrant, as shown in Figure 3B, to represent an alternate embodiment of a disposable cartridge assembly in association with an alternate embodiment of a blood perfusion system according to an alternate embodiment of this invention.

The specification has been amended to clarify all of Figures 3 and to delete reference to Figure 7C.

Specification

The specification has been amended to identify all of Figures 3 and to delete Figure 7C.

Rejection Under 35 U.S.C. 102

Claims 1-3 and 9-12 have been rejected under 35 U.S.C. 102(b) over U.S. Pat. No. 5,462,416 to Dennehey, et al. ("Dennehey"). It is axiomatic that, in order for a reference to anticipate a claim, a reference must have all elements of the claim arranged as they are in the claim. It is respectfully submitted that, with the present amendments to the claims, Dennehey does not anticipate any of the pending claims.

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Claim 1 requires an extracorporeal blood perfusion system for receiving venous blood from a patient and returning oxygenated blood to the patient in a cardiopulmonary bypass procedure, that comprises a disposable assembly and a control unit. The disposable assembly includes a cartridge and interconnected tubing lines. The cartridge has internal fluid passageways. One of the tubing lines is fluidly interconnected with at least one of the fluid passageways. The disposable assembly has a blood circuit for receiving venous blood from the patient and transferring oxygenated blood to the patient in a cardiopulmonary bypass procedure. The control unit has a component interface region. The component interface region includes a cartridge interface region for operatively interfacing with the cartridge, and a first pump for operatively interfacing with the blood circuit. The venous blood is pumped through the blood circuit by the first pump. The disposable cartridge has an internal cardiopulmonary passageway configured for operative connection to the cardiopulmonary circuit of the extracorporeal blood perfusion system, an internal cardioplegia passageway configured for operative connection to the cardioplegia circuit of the extracorporeal blood perfusion system, and an internal suction passageway configured for operative connection to the suction circuit of the extracorporeal blood perfusion system. Dennehey does not disclose or suggest an extracorporeal blood perfusion system with these specific features. Dependent claims 2-3 and 9-12 add further patentable features that are not shown or suggested by Dennehey.

Anticipation requires that the identical invention that is claimed was previously known to others and thus is not new. It is the Examiner's burden to show that every element of claims 1-3 and 9-12 is identically described in Dennehey. Dennehey shows a peristaltic pump tube cassette for a blood processing system, but does not show or suggest, alone or with other references of record, an extracorporeal blood perfusion system with a cardiopulmonary, cardioplegia and

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suction system for providing oxygenated blood to a patient in a cardiopulmonary bypass procedure. The terms of Dennehey are to be construed and understood as used by the Dennehey patent. The Examiner has not shown that one of ordinary skill in this art would understand that the peristaltic pump tube cassette and the blood processing system of Dennehey could be arranged as recited in the present claims.

The Examiner's assertions regarding failure to give patentable weight to recitations of functional language in the claims have no supportable merit. Features of an apparatus may be recited either structurally or functionally. There is nothing inherently wrong with defining some part of an invention in functional terms. MPEP §§ 2114, 2173.05(g). The Examiner provides no support for the requirement that "to be given patentable weight, a functional recitation must be expressed as a 'means' for performing a specified function." The present apparatus claims distinguish from Dennehey in terms of structure. Dennehey does not anticipate the present claims because it does not describe all structural limitations of the present claims, as stated in the above discussion.

The present rejection is in error and must be withdrawn.

Rejection Under 35 U.S.C. 103

In response to the Examiner's query regarding the inventive entity of the pending claims, the subject matter of the claims was commonly owned at the time the inventions claimed therein were made.

Claims 1-4 and 6-12 are rejected under 35 U.S.C. 103(a) as unpatentable over U.S. Pat. No. 5,385,540 to Abbott, et al. ("Abbott") in view of Dennehey. Applicants traverse this rejection as unsupported. The requirements of the presently rejected claims have been discussed above. There is no suggestion in Abbott or Dennehey or in any of the other art of record to combine the teachings of

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these two patents in the manner the Examiner proposes. Indeed, Abbott teaches away from the disclosure of Dennehey. Note that Abbott clearly teaches (col. 5, lines 26-29, *inter alia*) the use of a bladder pump, that "advantageously reduces the shearing forces and potential damage to which blood might be subjected in other pumps, such as peristaltic pumps." Dennehey is specifically concerned with peristaltic pumps (col. 1, lines 36-38, col. 23, line 2 - col. 26, line 4, *inter alia*). Accordingly, one of skill in this art, aware of the Abbott teaching against the use of peristaltic pumps, would find no motivation to incorporate the Dennehey teachings into the Abbott disclosure. In addition, the Abbott disposable cassette, FIG. 2, does not define "a blood circuit for receiving venous blood from the patient and transferring oxygenated blood to the patient," as required by present claim 1. The Abbott disposable cassette (col. 5, lines 19-53, *inter alia*) only provides cardioplegia solution to the blood and does not transfer oxygenated blood to the patient. Oxygenated blood is provided by a separate, prior art heart/lung machine (col. 2, lines 12-16, *inter alia*). Claims 2-4 and 6-12 add further patentable features that are not shown or suggested by Abbott and Dennehey. This rejection is unsupportable and withdrawal thereof is solicited.

Claim 5 is rejected under 35 U.S.C. 103(a) as unpatentable over Abbott in view of Dennehey, in view of U.S. Pat. No. 5,820,579 to Plotkin. Applicants traverse this rejection as unsupportable. The requirements of the presently rejected claims have been discussed above. There is no suggestion in Abbott, Dennehey or Plotkin or in any of the other art of record to combine the teachings of these patents in the manner the Examiner proposes. The differences between the Abbott and Dennehey teachings have been discussed in the remarks *supra* and are incorporated here as equally applicable. Plotkin does not supply the deficiencies of these two references. Indeed, Plotkin teaches away from the disclosure of

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Abbott. As discussed in the remarks *supra*, in regard to the Abbott disposable cassette, Abbott recommends the use of a bladder pump. Plotkin, by contrast, denigrates the use of bladder pumps (col. 1, lines 59-67, *inter alia*), because they tend to be more mechanically complex ... and do not lend themselves to ... low cost manufacture for one-time disposable use. Increased blood trauma is experienced in these pumps due to the multiple check valves in the flow path and stagnant areas due to less than perfect chamber filling and ejection.

Note the multiple check valves 84, 86, 88, 90, 92, 94 in the disposable cassette of Abbott (Fig. 2, and the discussion thereof in the specification).

This rejection is unsupportable and withdrawal thereof is solicited.

Conclusion

It is respectfully submitted that this application is in condition for allowance and a formal notice to that effect is respectfully requested to be forthcoming. Should any minor matters remain prior to the issuance of a notice of allowance, the Examiner is requested to telephone the undersigned attorney to reach prompt resolution thereof.

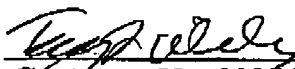
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If any additional fees are due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 16-2312. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our deposit account.

Respectfully submitted,

Date: 12/10/03

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